## REMARKS

Applicants have read and considered the Office Action dated January 29, 2003 and the references cited therein. Claims 41 to 80 remain pending in the application.

Reconsideration of this Application and entry of the foregoing amendments are requested. Claims 41-42, 48-52, 57-59, 62-63, 66-73 and 76-79 have been amended in view of the Office Action and to better define what the Applicants consider their invention, as fully supported by an enabling disclosure.

## REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 42, and dependent claims 45-46, 48 and 71 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants respectfully traverse the rejection as follows:

Applicants have amended claims 42 and 71 to more clearly and specifically describe the present invention. The term "bactericidal amount of a bactericide" in claims 42 and 71 has been replaced by "effective amount of a bactericide". Applicants respectfully submit that this amendment overcomes the indefiniteness rejection since it is clear that a bactericide has to be added in an effective amount to perform its task. Applicants further submit that claims 42 and 71 have been amended to recite that the composition comprises a bactericide and that therefore there is no step of "providing a bactericide". It is respectfully submitted that the rejections of claims 45, 46, and 48 have been overcome by the foregoing amendment.

Claim 41 was rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants have amended claim 41 to define that the acid is a salt-forming acid, such that the salt is required and has the enumerated characteristics.

Claim 79 was rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants have amended claim 79 by deleting the term "about".

In view of the above and foregoing, it is respectfully requested that the Examiner withdraw his rejection of claims 41, 42, 45, 46, 48, 71 and 79 under 35 U.S.C. § 112, second paragraph.

**OBJECTIONS UNDER 37 CFR 1.75(c)**

Claims 42, 69 and 73 were objected to under 37 CFR 1.75(c) as being of improper dependent form. Applicants respectfully traverse the rejection as follows:

Applicants have amended claims 42, 69 and 73 to recite that the composition further comprises a bactericide, and not the method. Furthermore, Applicants have amended claim 41 to correct a spelling mistake.

In view of the above and foregoing, it is respectfully submitted that all the claim objections have been addressed.

**REJECTIONS UNDER 35 U.S.C. § 103(a)**

Claims 41-80 have been rejected as being obvious in view of USP 5,731,275 and Nishiguchi *et al.* under 35 U.S.C. § 103(a).

Applicants respectfully traverse the rejection as follows:

Claims 41-80 have been rejected for a lack of inventiveness in view of Applicants' own patent (USP 5,73,275). Applicants respectfully disagree.

The '275 reference is restricted to a few compositions that are disclaimed from the present claims and, as the Examiner points out, the '275 patent fails to explicitly disclose a composition outside the indicated excluded range. Applicants respectfully submit that there is no teaching or suggestion in the '275 reference of how specific components attack the integrity of the biofilms, *e.g.* there is no mechanism of action proposed that would lead to the establishment of a generic class of components useful for the purpose of removing biofilms with high efficacy.

The present disclosure, on the other hand, teaches that efficient biofilm removing solutions can be minimally composed of a detergent and a salt-forming acid at a working pH. The action of the salt, monovalent sodium in the preferred case, is to replace the divalent calcium involved in maintaining the integrity of the exopolysaccharides (EPS), the "sticky" constituent of biofilms. The present disclosure reports a large number of acids that support this conclusion. Furthermore, the present disclosure teaches that a compound having bactericidal properties may be added to the minimal detergent plus salt-forming acid if a biofilm-removing bactericidal composition is desired.

The Examiner further states that it would have been obvious to use different quantities of SDS for the purpose of the present invention considering the teachings of Nishiguchi and Hames. The Examiner further cites Hames and Nishiguchi and relates the detergent properties of SDS to protein denaturation, cell lysis and a DNA extraction protocol from fresh or fixed tissue in support of the obviousness rejection of claims 41-80.

Applicants respectfully disagree because the cited references pertain to totally different problems that are not related to dislodging biofilms. Indeed, biofilms are complex associations of cells, extra cellular products and detritus either trapped within the biofilm or released from cells that have lysed as the biofilm aged. The main "cement" for all these cells and products is the mixture of exopolysaccharides (EPS) secreted by the cells established within the biofilm. The removal of the latter therefore requires attacking the integrity of the exopolysaccharide matrix where divalent calcium, hydrogen bonding and hydrophobic forces are involved in linking these polymeric chains together. As indicated above, the present disclosure teaches the generic minimal composition of a detergent and a salt-forming acid to the dismantlement of biofilms. The disclosure also teaches the possible adjunction of a compound having bactericidal properties to obtain a generic bactericidal biofilm dislodging composition.

Applicants respectfully submit that Nishiguchi and Hames do not provide any motivation to use the presently claimed components for the purpose of dislodging a biofilm. Applicants' previous patent discloses a very restricted set of compositions that can be used for dislodging biofilms. Applicants have worked extensively on this invention for extended periods in order to find any non-obvious equivalents to the previously claimed compositions. Applicants have discovered an impressive list of salt-forming acids that can all replace mandelic and/or lactic acids in cleansing solutions. The gap between Applicants' previous patent and the present invention is certainly not taught or even suggested by the references of Nishiguchi and Hames or any combination of the references.

The Examiner has also cited USP 5,942,480, 5,759,970 and 5,910,420 against the present claims on page 6 of the Office Action. The Examiner states that the use of the term "about" in the cited patents anticipates the present claims 41, 68, 70 and 76.

Applicants have amended claims 41, 68, 70 and 76 by adding the term "about" to any concentration already disclosed in these cited references, and which are expectedly excluded in a proviso clause. Applicants would like to make it clear that there should be no overlap and

anticipation between Applicants' previous patents and the present application. Whatever the concentration claimed in these previous patents, they are not the subject of the present claims and do not suggest the present claims when each and all of these ingredients are used together.

With regard to the applicability of US Patent 5,910,420 against the present claims, Applicants wish to draw the Examiner's attention to the fact that the purpose of the cited method is to preserve the viability of the microorganisms while detaching the same from a surface. Example 4 illustrates a composition comprising 1% SDS, 0.07% EDTA, 1% DTT and 0.01% trisacetate buffer pH 7.75. The conclusion of the inventors was that the addition of detergent did not significantly increase the removal of bacteria although the replicability of the removal was better. The inventors further note that SDS and BRIJ 35 were more successful in removing a biofilm than a mixture of EDTA and DTT. In addition, Table 4 shows no complete removal of the microorganism.

Applicants asset that all the features of the presently claimed method are not taught or suggested by the '420 patent or any combination of cited references. These features are the presence of a detergent and of a salt-forming acid. There apparently is no "effective amount of a salt-forming acid" in the '420 patent, so there is no complete biofilm removal. The purpose of the presently claimed method being different (if not opposite) from the one in the cited reference, the composition used in both methods should be different. In the alternative, if the compositions were the same, their use would differ from another, because the cited reference aims at preserving the viability of the dislodged microorganism.

In view of the foregoing, it is believed that the rejections of the claims have been overcome by the present remarks and amendments, and that the presently claimed method is original and patentable and is in a condition for allowance. If a telephone interview would be helpful in this matter, please contact Applicants' Representative at (612) 336-4728.

Respectfully submitted,

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## AMENDMENTS TO THE CLAIMS

This listing of claims will replace prior versions and listings of claims in the application:

**Listing of claims:**

Claims have been amended as follows: Underlines indicate insertions and ~~strikeouts~~ indicate deletions.

41. (Currently amended) A method for removing a biofilm from a surface, which comprises the step of contacting said surface with a composition comprising an effective dislodging amount of a detergent and an effective dislodging amount of ~~an acid or a salt of an acid,~~ a salt-forming acid, said salt being capable of displacing divalent cations present in the structure of said biofilm, with the proviso that said composition is not a mixture achieving an aqueous final concentration of about 1% to about 2% SDS ~~1% - 2%~~ and about 1% EDTA ~~1%~~, or about 1% to about 2% SDS ~~1% - 2%~~ and mandelic and lactic acids, each at an individual concentration of about 1% or in a combined concentration of about 2%, for a time sufficient to ~~dislodge~~ dislodge said biofilm, all percentages representing weight per volume concentrations.

42. (Currently amended) A method as defined in claim 41, wherein said composition further ~~comprising~~ comprises an effective ~~bactericidal~~ amount of a bactericide.

43. (Original) A method as defined in claim 41, wherein said detergent is SDS, which achieves, once reconstituted in an aqueous solution, a concentration of at least about 0.1 % or any detergent having a biofilm dislodging potency substantially equivalent thereto.

44. (Original) A method as defined in claim 43, wherein said equivalent detergent is CPC or CPB at a concentration of at least about 0.5%.

45. (Original) A method as defined in claim 42, wherein said detergent is SDS, which achieves, once reconstituted in an aqueous solution, a concentration of at least about 0.1 % or any detergent having a biofilm dislodging potency substantially equivalent thereto.